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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---------------------|-------------|----------------------|----------------------|------------------|
| 10/542,253 | 03/23/2006 | Alessandro Martini | PC27894A | 5093 |
| 25533 | 7590 | 01/07/2009 | EXAMINER | |
| PHARMACIA & UPJOHN | | | SULLIVAN, DANIELLE D | |
| 7000 Portage Road | | | | |
| KZO-300-104 | | | ART UNIT | PAPER NUMBER |
| KALAMAZOO, MI 49001 | | | 1616 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 01/07/2009 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/542,253 | MARTINI ET AL. | |
| | Examiner | Art Unit | |
| | DANIELLE SULLIVAN | 1616 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 14 July 2005.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-18 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-4 and 14-18 is/are rejected.
 7) Claim(s) 5-13 is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/03/2005</u> . | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Specification

The use of the trademarks Labrasol, Labrafil M2125, Labrafil M1944, Gelucire 44/14 and Lutrol F68 have been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Objections

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 5-19 been renumbered 4-18.

Claims 5-13 objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must be recited in the alternative. See MPEP § 608.01(n). Accordingly, the claims 5-13 not been further treated on the merits.

Claims 1-4 and 14-18 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 4 and 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. The claim specify the indolinone derivative is selected from the group consisting of SU 5416, SU 6668, SU 10944, SU 10994, SU 14813, SU 11248 and the respective pharmaceutically acceptable salt forms. In view of Ex parte Fressola, 27 USPQ2d 1608 (Bd. Pat. App. & Int. 1993), claims must stand alone to define invention and incorporation by express reference to the specification is not permitted except in very limited circumstances. Therefore, the indolinone derivative must further limit a specific structure of formula (I).

Claims 14-17 provide for the use of a compound, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 18 recites the limitation "molten carrier" in reference to the carrier in claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 101

Claims 14-17 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

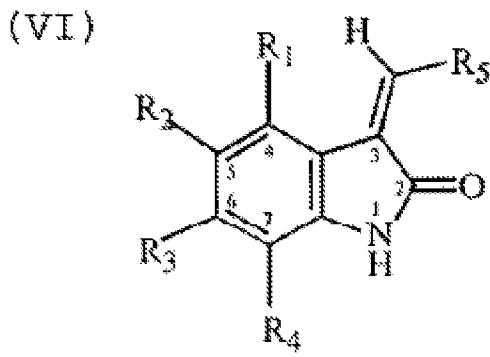
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 and 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Shenoy et al. (WO 98/38984).

Shenoy et al. disclose a formulation comprising hydrophobic pharmaceutical agents selected from indolinone-based compounds and one or more pharmaceutically acceptable surfactants (page 3, lines 20-27). The compound of formula (VI) preferably contains a pyrrolic ring in the R₅ position. Preferably, the compound is 3-{(2,4-dimethylpyrrol-5-yl) methylene]-2-indolinone (page 22, line 3 thru page 23, line 5).



The surfactants that may be selected

include polyglycolized lipids preferably Gelucire 44/14 and Labrasol (page 31, line 22 thru page 32, line 2; page 39, lines 8-10). The formulation is contained in semisolid/solution or solid form for oral administration (page 43, lines 2-8). Table 5 discloses a formulation comprising 3% indolinone, Gelucire 44/14, polyethylene glycol, Miglyol 812, Cremophor EL and Labrasol (page 90, line 5-21). Drug concentration may

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be increased or decreased without modification to the rest of the formulation (page 87, lines 17-26).

Shenoy et al. teach a method of making the formulation by dissolving the drug into the surfactant then placing the mixture into a gelatin capsule (page 91, lines 17 thru page 92, line 10).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANIELLE SULLIVAN whose telephone number is (571)270-3285. The examiner can normally be reached on 7:30 AM - 5:00 PM Mon-Thur EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Danielle Sullivan
Patent Examiner
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/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616